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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,896	01/09/2002	Anan Chuntharapai	GENENT.074A	1225

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EXAMINER	
CHAUDHURI, ANIRUDDHO RAY	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,896	CHUNTHARAPAI ET AL.	
	Examiner	Art Unit	
	Aniruddho R Chaudhuri	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Sequence Compliance

The instant application is in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, 42-48, drawn to an anti-IFN-.alpha.antibody, pharmaceutical compositions and hybridomas classified in Class 424, subclass 130.1; Class 435, subclass 335; and Class 530, subclass 388.23.

II. Claims 31-40, drawn to an isolated nucleic acid molecule, vector and host cell, classified in Class 530, subclass 23.53; Class 435, subclasses 320.1 and 325.

III. Claim 41, drawn to a method of producing an antibody, classified in Class 435, subclass 70.21.

IV. Claim 49, drawn to a method of diagnosing a condition associated with the expression of IFN-.alpha, classified in Class 435, subclass 7.1.

V. Claims 50-54, drawn to a method of treating disease associated with the expression of IFN-.alpha, classified in Class 424, subclass 145.1.

1. Groups I and II are different products. Nucleic acids, vector, host cells and antibodies differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct. Therefore, they are patentably distinct.

2. Groups III, IV and V are different methods. These inventions are different with respect to ingredients, method steps, and endpoints, which require non-coextensive searches; therefore, each method is patentably distinct.

3. Groups I and III are related as products of methods of culturing cells to express said products. The method steps do not define the structure of the claimed products. Therefore, they are patentably distinct.

4. Groups I and IV/V are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-IFN.alpha.antibody of Group I can be used for affinity purification, in addition to the methods of treating and diagnosing recited.

5. Groups II and III/IV/V are not related as product and process of using.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed inventions wherein

7. *If Group I - IV is elected:* Applicant is required to elect a particular specificity of an anti-IFN.alpha.antibody, (e.g. IFN.alpha.1, IFN.alpha.2, IFN.alpha.3, IFN.alpha.4, IFN.alpha.5, IFN.alpha.8, IFN.alpha.10, IFN.alpha.21).

Applicant is invited to clarify whether the anti-IFN.alpha.antibody binds and neutralizes in all the IFN.alpha subtypes, that is, an antibody that binds one IFN subtype will bind all IFN subtypes.

In addition, applicant is further required to elect a particular anti-IFN.alpha.antibody and to provide the following information with respect to the elected species of anti-IFN.alpha.antibody:

i) applicable CDR SEQ ID NOS: from claims 20, 22 and 24,

ii) relationship (if any) to the antibodies recited by clone designation in, e.g., claim 10,

These species of anti-IFN.alpha.antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen-binding site.

Further it appears that anti-IFN-.antibodies bind distinct interferon specificities, where the structure of the claimed target interferon specificities differ.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

8. *If one of the Groups IV - V is elected*: Applicant is required to elect a disease for diagnosing a condition or for treating a disease condition using an effective amount of anti-IFN-.alpha.antibody (e.g. one of the specific diseases recited in claim 54).

These species are distinct because the diseases differ with respect to their etiologies, the patient populations involved, and their therapeutic endpoints; thus each specific method of diagnosis and treating each of the diseases represents patentably distinct subject matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aniruddho Ray Chaudhuri whose telephone number is 571-272-0953. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 13, 2004

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